

REMARKS

The Examiner has noted that a certified copy of Swedish Patent Application No. 0100938-0 has not been submitted. Please note that a certified copy was filed with the United States Patent and Trademark Office on October 15, 2008.

The drawings have been objected to under 35 U.S.C. 132(a) as adding new matter.

The figure legends and references were included in the PCT application. The figure legends were included on page 16 of the PCT application page 8, line 30 for Figure 8 and on page 9, line 29 for Figure 9. The figures are also mentioned on page 5, lines 27 and 29, but they were switched, i.e. the text regarding the fusion protein refers to Figure 9 and the text regarding the fusion gene and the southern blot analysis refers to Figure 8, and they should be the other way around. The figures were also present in the Swedish priority application. Thus, the Applicant does not believe that the figures are new matter as they were referenced in the priority applications which are now claimed and thus, no new matter has been added.

The Examiner has stated that Information Disclosure Statement filed on September 12, 2003 fails to comply with the provisions of 37 CFR §1.97, 1.98 and MPEP §609 because it does not include a concise explanation of the relevance of the information of each patent, publication, or other information listed that is not in the English language.

The Applicant's attorney has spoken with the Examiner, who agreed that the previously filed Information Disclosure Statement is in proper order.

Claim 39 has been rejected under 35 U.S.C. §112, first paragraph, enabling requirement.

The Examiner's rejection is respectfully traversed.

Claims 39 as now amended is directed to a method for diagnosing the presence or absence of a squamous cell carcinoma by detecting the presence and concentration of the

SCCA1/SCCA2 fusion protein in a human sample using a monoclonal antibody specific for the SCCA1/SCCA2 fusion protein only. The monoclonal antibody has less than 5% cross reactivity for the SCCA1 or SCCA2 antibody. The SCCA1/SCCA2 fusion protein is coded by the exons 2-7 of the SCCA1 gene fused to exon 8 of the SCCA2 gene the amino acid sequence of the SCCA1/SCCA2 fusion protein being SEQ ID NO: 1.

Claim 39 has been amended in accordance with that shown in Example 5.1 of the specification, wherein the experiment demonstrates the use of antibody SCC106 which is specific for the SCCA1/A2 protein in an immunoassay. Furthermore, in a previous office action (dated 02/07/2008) the Examiner objected to the specification as not disclosing "the SCCA1/A2 fusion protein naturally exists. The specification does not show that the SCCA1/SCCA2 fusion protein is differentially expressed in SCC cells compared to normal cells, and is correlated to the presence of SCC." Attached hereto, please find experimental data (performed in accordance with those described in the materials and methods section) that shows the SCCA1/A2 protein is expressed in SCC cells and not in normal cells. The experiments also show that the SCCA1/A2 protein can be detected in SCC cells using the SCC106 antibody described in the application as filed.

In view of the foregoing, the Applicants believe that pending claim 39 is in a condition for allowance and now should be allowed.

The application is now considered to be in condition for allowance, and an early indication of same is earnestly solicited.

The Commissioner is authorized to charge any further extension and/or fee that is required to Deposit Order Account 19-0079.

Respectfully submitted,



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